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Report Highlights:
China is currently the sixth largest producer of biotechnology enhanced plants (primarily Bt cotton) based on total acreage (3.5 million hectares in 2010). The central government is actively fostering the agriculture biotech industry as an emerging strategic sector during the 12th five-year-plan (2011-2016). However, public concerns over biotech product safety have made the regulators more cautious about commercializing biotech food/feed crops.

Section I. Executive Summary:

Current trends suggest that China will remain a significant importer of biotech products and may become an exporter of biotechnology in the medium to long term. China is currently the sixth largest producer of biotechnology enhanced plants based on total acreage (3.5 million hectares in 2010), and the central government is actively fostering the agriculture biotech industry as an emerging strategic sector for the country. China's Ministry of Agriculture issued biosafety certificates for biotech rice and corn in November 2009, the first time for a staple food crop. However, Chinese biotech regulations and application procedures for new products lack transparency, and currently no foreign biotech crops for domestic commercial production have been approved.

In June 2009, the State Council released policy guidelines to promote the accelerated development of the biotechnology industry to support the *11th Five-Year-Plan on the Development of the Biotech Industry*. The objectives of the policy initiatives were to consolidate resources for biotechnology innovation and commercialization, develop domestic technologies, and nurture both a handful of Chinese owned globally competitive biotech companies and SMEs (See Gain Report CH9061). The *12th Five-Year-Plan on the Development of the Biotech Industry* is being finalized by the National Development and Reform Commission (NDRC), which reportedly carries the same message. In July 2008, the State Council approved a special program to develop new biotech varieties, which could include investment totaling as high as USD $3.5 billion before 2020.

China's regulatory infrastructure is still developing, and includes biotech regulations that present market access impediments. The barriers include asynchronous approval, which requires that a product must be fully approved in the originating country before an application can be filed for approval in China, inadequate protection for intellectual property rights, a restrictive low level presence threshold of 0 percent, and no clear policy on stacked events.

Despite the central government's investments and support of biotechnology, current Chinese consumer opinion appears somewhat mixed, which will require greater efforts from the Chinese government to educate the population on the advantages and safety of biotech foods. Otherwise, it may experience difficulty in fully realizing the benefits of biotechnology to help address its food security challenges.

Section II. Plant Biotechnology Trade and Production:

Biotechnology Crop Production

China has commercialized six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya). According to an International Service for the Acquisition of Agro-biotech Applications (ISAAA) report, China is now the sixth largest producer of agricultural biotechnology crops in the world by acreage (behind the United States, Brazil, Argentina, India, and Canada) at 3.5 million hectares in 2010. Insect-resistant (Bt) cotton is the single largest biotechnologically enhanced product produced in China. It is estimated that, in 2010, more than 67 percent of the 5.2 million hectares of all cotton planted in China is produced with Bt cotton varieties. Almost all of the GM plants deregulated by MOA for commercial production are not currently being produced since their biosafety certificates expired and were not renewed (lack of a commercial market). Only a virus resistant papaya is still produced in Guangdong on approximately 3,500 hectares. In addition, in 2002 the State Forest Administration (SFA) deregulated and commercialized 2 genetically modified forestry plants, namely insect resistant poplar 12 and poplar 741, which are planted on 333 hectares.

Domestic Biotechnology Crop Development

On November 27, 2009, the Ministry of Agriculture (MOA) granted biosafety certificates to two insect resistant rice varieties and a high phytase corn variety. This was the first time the Chinese government has granted biosafety certificates to major food and feed crops. In addition to the biosafety certificates, both products must still complete the plant variety registration process before they can be officially commercialized. MOA has mentioned that because these are GM crops, the variety registration process may take up to 5 years or possibly longer.

MOA and SFA do not publish information on ongoing Chinese research and development. According to MOA publications, other major crops undergoing the field trial stage of development which is either the intermediary experiment or environmental release stage; see Approval for Domestic Production section) include insect resistant corn, high lysine corn, wheat resistant to pre-harvest germination, and insect resistant soybeans.

Post believes that the central government's primary interest in biotechnology is to address food security. Almost all biotech

research and development is carried out by public-funded research institutes and universities. China has heavily invested in biotech research, but has not successfully developed many biotech products that can be commercialized. In July 2008, the State Council approved a special research program on the development of new biotech varieties with an investment that could total as much as USD $3.5 billion (funding to be allocated by central and local governments as well as investment by companies) over the next 12 years. It is reported that the investment in the special research program has already exceeded $4.0 billion by the end of 2010. According to the "Long and Mid-term National Development Plan for Science and Technology (2006-2020)", the program will focus on crop research (rice, wheat, corn, and cotton) and animal research (swine, cattle, and sheep). The target is to develop new varieties with traits such as insect, disease, and stress resistance, and high yields.

Private sector research and development in agricultural biotechnology is limited and highly regulated. Chinese biotech seed development is conducted by public research institutes and universities funded by various parts of the Chinese government, though marketing is often done by affiliated private companies. Foreign investment on research and production of biotech plants, livestock, and aquatic products is prohibited. Foreign investment is allowed in conventional/hybrid seed production, but is restricted to minority shareholders in joint ventures with Chinese companies.

Ministry of Agriculture: Import Approval Procedure

The Ministry of Agriculture is responsible for approving imported biotechnology products. The approval process varies depending on the product's intended use (research, processing, or production), safety levels, and the potential threat of the organism to human or animal health and the environment. MOA Decree 9 (See Gain Report CH7053) outlines the different requirements for importing biotech products with different purposes.

For the importation of products as processing materials, Decree 9 states that a foreign seed developer must apply for an agricultural biotech biosafety certificate from MOA's Division of GMO Biosafety and IPR. The regulations require applicants to provide a variety of materials and certification that the exporting country has allowed use and sale of the product in its domestic market, and that it has undergone tests showing no harm to animals, plants, or the environment. MOA also requires authorized domestic institutions to conduct environmental safety (field trials) and food safety (animal feeding) tests to verify data provided by the seed developer. All these documents, including reports generated from verification tests, must be reviewed by the National Biosafety Committee before MOA can issue a biosafety certificate.

Although the regulation provides that MOA should respond to an application for a biosafety certificate within 270 days, the approval processes varies from crop to crop depending on its intended use and potential impact on human or animal health and the environment. In general, the process of getting a biosafety certificate for imported biotech food crops for processing (like soybeans) will last about two years. It involves steps of varying length, such as importing testing materials, field trials and/or a feeding study, and an evaluation by the NBC.

Ministry of Agriculture: Domestic Production Approval Procedure

To produce biotech crops domestically in China, technology providers must pass a biosafety evaluation by the National Biosafety Committee and issued a biosafety certificate by the MOA's Division of GMO Biosafety and IPR. As outlined below, the approval process for biotechnology products for domestic cultivation involves five steps: research, intermediary experiment, environmental release, productive testing, and biosafety certification. Approvals are also sought at the provincial level. After completing the five steps, products are eligible for biosafety certificates.

In February 2008, the Ministry of Agriculture announced that Bt cotton varieties that received biosafety certificates for commercial production may apply for production in all ecologically suitable areas [See Section: Approved Domestic Biotechnology Crops]. For other biotech crops, a biosafety certificate is applicable only to the province or region where the original application was made.

In addition to a biosafety certificate for commercial production, biotech seed developers must register the biotech variety at the provincial agricultural department (and/or at the national level) as required by the Seed Law. (Note: in some provinces this process may begin in step 4 of "production testing" and therefore can save one year).

According to a joint notification by NDRC and the Ministry of Finance to the Ministry of Agriculture, a fee charge schedule

for the safety evaluation and testing of agricultural GMOs is summarized as follows:

1. Intermediary experiment (2,500 yuan per item)
2. Environment release (3,000 yuan per item)
3. Productive testing (5,000 yuan each or 3,000 yuan for additional imports as processing materials)
4. GMO Survival and Competiveness Test (83,000 yuan per item)
5. Ecological Risk of Gene Flow Test (92,000 yuan per item)
6. GMO Impact on Non-target Organisms and Biodiversity Test (96,000 yuan per item)
7. Anti-nutrient Test (1,000 yuan per item)
8. 90-day Rat Feeding Study (120,000 yuan per item)

A rough outline of the GMO application process is listed below. The names of institutions and contacts are provided as available.

1. MOA open window: accepts applications.
   Contact: Mr. Lian Qing
   Tel: 5919-1811
2. Biosafety Management Division at the Center for Science and Technology Development (CSTD) reviews and submits the application to the National Biosafety Committee (NBC).
   Contact: Mrs. Li Ning
   Tel: 5919-5089
3. NBC plenary sessions are heldin March, July and November to discuss applications and determine appropriate tests.
4. Division of GMO Biosafety and IPR processes import permit for field trials and a feed studies based on NBC recommendations.
   Contact: Ms. Sun Junli
   Tel: 5919-3059
5. Detection and Testing Division at the Center for Science and Technology Development designates testing institutes and locations for field trials and a feed study, and works with applicants and designated testing institutes to understand the applicant's testing methods and sampling process. The testing institutes may or may not use the same processes or methods while conducting its own tests.
   Contact: Mr. Song Guiwen
   Tel: 5919-5096
6. Provincial Agriculture Bureaus endorse field trials based on the Division of GMO Biosafety and IPR approvals.
7. Testing institutes draft reports after the field trials and feed studies are completed.
8. Biosafety Management Division of CSTD reviews and submits a final version of all analysis to NBC.
9. NBC reviews the field trial and feed study reports, and provides a recommendation for approval;
10. The Division of GMO Biosafety and IPR takes NBC's recommendation into consideration before issuing a biosafety certificate to the applicant.

State Forestry Administration: Domestic Production and Import Approval Procedure

The State Forestry Administration (SFA) regulates research, production and import/export of biotech engineered trees that are intended for forestation and wood processing. This does not include trees that grow fruits, nuts, or other consumable products (these plants fall under the jurisdiction of MOA). The SFA deregulatory process is similar to MOA's. Depending on transgenic tree risk levels, SFA will give approval for developers to conduct lab research. The deregulation of a biotech tree includes 3 stages: intermediary trial, environmental release, and productive testing. After a domestic developer completes each stage, he/she must submit a document containing all the data and material from the study to SFA, who will provide a determination, within 20 working days, on whether the deregulatory process can continue to next stage. If SFA believes that a further risk assessment is needed, the time-frame between stages may be longer. After all the stages are successfully completed, a biosafety certificate will be issued, which is valid for 2 years. However, before the product can be commercialized, the biotech tree also must undergo a seed variety registration process (just like MOA), which may include an additional assessment by experts from government, academia, and/or private industry. This process takes about one year for non-GM product, but may take longer for GM product since additional field trials may be needed.

Imported biotech tree products intended for production and processing are not required to undergo field trials. However, in order to acquire approval for import, foreign developers must provide documentation that the product has been deregulated by a third country and will certify that the product is 100% safe for humans, plants, animals, microorganisms, and the

environment. Because no foreign developer can certify that a product is 100% safe, no foreign GM product has entered China's market to date. Other requirements may be needed. A biotech tree intended for domestic cultivation must also undergo the SFA variety seed registration process.

Approved Imported Biotechnology Crops

MOA has approved the importation of five biotech crops/products for processing or feed use (soybeans, corn, canola, cotton and sugar beets). SFA has not approved any imported biotech trees. In 2010, the United States exported more than USD $11.3 billion (23.6 million MT) of soybeans and USD $2.0 billion (one million MT) of cotton to China, most of which were biotech varieties. In 2004, China granted its first biosafety certificates to import foreign products. The current import list of biotech events approved for processing is listed below:

Biotech crops approved by MOA for import as processing materials (as of March 21, 2011)

Crop	Trait	Event	Developer	Bioafety certificate validity
Cotton	Insect resistance	Bollgard II (15985)	Monsanto	7/20/2006-7/20/2011
Cotton	Herbicide tolerance	LLCOTTON25	Bayer CropScience	12/20/2006-12/20/2011
Cotton	Herbicide tolerance	MONey88913	Monsanto	12/20/2007-12/20/2012
Cotton	Insect resistance	531	Monsanto	08/28/2008-08/28/2013
Cotton	Herbicide tolerance	1445	Monsanto	08/28/2008-08/28/2013
Soybean	Herbicide tolerance	MON89788	Monsanto	08/28/2008-08/28/2011
Corn	Herbicide tolerance	GA21	Syngenta	08/28/2008-08/28/2011
Corn	Insect resistance	MIR604	Syngenta	08/28/2008-08/28/2011
Corn	Herbicide tolerance	T25	Bayer CropScience	4/20/2009-4/20/2012
Canola	Herbicide tolerance	T45	Bayer CropScience	4/20/2009-4/20/2012
Canola	Herbicide tolerance	Oxy-235	Bayer CropScience	4/20/2009-4/20/2012
Canola	Herbicide tolerance	Ms8Rf3	Bayer CropScience	4/20/2009-4/20/2012
Sugar beet	Herbicide tolerance	H7-1	Monsanto	4/20/2009-4/20/2012
Soybean	Herbicide tolerance	GTS40-3-2	Monsanto	12/20/2009-12/20/2012
Corn	Insect resistance	59122	Du Pont/Dow AgroSciences	12/20/2009-12/20/2012
Corn	Insect resistance	TC1507	Du Pont/Dow AgroSciences	12/20/2009-12/20/2012
Corn	Insect resistance	MON810	Monsanto	12/20/2009-12/20/2012
Corn	Insect resistance	MON863	Monsanto	12/20/2009-12/20/2012
Corn	Insect resistance	BT176	Syngenta	12/20/2009-

				12/20/2012
Corn	Insect resistance	BT11	Syngenta	12/20/2009-12/20/2012
Canola	Herbicide tolerance	Topas19/2	Bayer CropScience	12/20/2009-12/20/2012
Canola	Herbicide tolerance	Ms1Rf1	Bayer CropScience	12/20/2009-12/20/2012
Canola	Herbicide tolerance	Ms1Rf2	Bayer CropScience	12/20/2009-12/20/2012
Canola	Herbicide tolerance	GT73	Monsanto	12/20/2009-12/20/2012
Soybean	Herbicide tolerance	A2704-12	Bayer CropScience	12/20/20010-12/20/2013
Corn	Herbicide tolerance	NK603	Monsanto	12/20/20010-12/20/2013
Corn	Insect resistance & herbicide tolerance	MON88017	Monsanto	12/20/2010-12/20/2013
Soybean	Herbicide tolerance	356034	DuPont	12/30/2010-12/30/2013
Corn	Insect resistance	MON89034	Monsanto	12/30/2010-12/20/2013
Cotton	Insect resistance	15985	Monsanto	7/21/2011-7/21/2016
Cotton	Herbicide tolerance	GHB614	Bayer CropScience	12/30/2010-12/30/2015
Soybean	Herbicide tolerance	MON89788	Monsanto	8/29/2011-8/29/2014

Approved Domestic Biotechnology Crops

A list of biotech products that have been approved for commercial production in China is available on MOA's web site at http://www.stee.agri.gov.cn/biosafety/spxx/. A full list is not provided in this report. SFA provides no public reports on its deregulated products. For MOA, although over 200 varieties are approved, almost all of the approvals are Bt cotton varieties. Three ecological areas are eligible for the cultivation of Bt cotton, but this does not apply to other biotech crops which must apply on a provincial basis. For Bt cotton, the ecological areas include the Yangtze River Reaches (covering Sichuan, Chongqing, Hubei, Hunan, Jiangxi, Zhejiang, Jiangsu (not including Xuzhou), Huainan of Anhui, and Nanyang and Xinyang of Henan), Yellow River Reaches (covering Huaibei of Anhui, Shandong, Xuzhou of Jiangsu, Henan (not including Nanyang), Hebei, Beijing, Tianjin, Shaanxi, and Shanxi), and the Northwestern inland area (covering Xinjiang, Gansu, Ningxia, and Inner Mongolia).

Section III. Plant Biotechnology Policy:

Ministerial Responsibilities

MOA is mainly responsible for the approval of biotech agricultural crops for import and domestic production, as well as creating biotech policy. It also manages and distributes central government funds to Chinese institutes and universities for the research and development of biotech crops (this responsibility was formally under MOST). The State Forestry Administration (SFA) is responsible for the approval of forestry products for research, domestic production, and import, and also creates its own biotech regulatory policies. MEP (formerly the State Administration of Environmental Protection (SEPA)) is the lead agency for the negotiation and implementation of the Biosafety Protocol (BSP), which China ratified on April 27, 2005. The General Administration of Quality, Inspection, and Quarantine (AQSIQ) and its local inspection and quarantine offices (CIQs) are responsible for the nationwide management of inspection and quarantine for the entry and exit of all biotech products. AQSIQ's Ministerial Decree 62 (See Gain Report CH4017) governs the steps that should be taken at customs when importing or exporting biotech goods.

MOA established the National Biosafety Committee (NBC), which is a regulatory team of 74 experts with multidisciplinary backgrounds from nine ministries, nine research institutions, and nine universities, to evaluate domestic and foreign applications for biosafety certificates for biotech products. The Committee is divided into three expert groups: biotech plants, animals and microorganisms, and food and feed. Since 2008, the Ministry of Agriculture announced that the NBC will increase the number of meetings from two to three a year, which usually occur in March, July, and November. Final decisions are generally released 45 days after each deadline.

The National Technical Committee for the Standardization of Biosafety Management of Agricultural GMOs consists of 41 experts and administrative officials, and is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detections.

There are 49 MOA-authorized centers across the country, which undertake environmental safety testing, food safety testing, and detection of agricultural GMOs.

The MOA provincial level departments are responsible for monitoring field trials of biotech products, GMO processing facilities, the seed market, and labeling.

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms (GMOs) meets irregularly to discuss and coordinate major issues in the biosafety management of biotech agricultural products. The conference consists of seven government agencies under the State Council that include: the Ministry of Agriculture (MOA), National Development and Reform Commission (NDRC), the Ministry of Environmental Protection (MEP), the General Administration on Quality and Supervision, Inspection and Quarantine (AQSIQ), the Ministry of Science and Technology (MOST), the Ministry of Commerce (MOFCOM), and the Ministry of Health (MOH). The conference has little decision making authority, and mostly is a forum used for coordination purposes if a biotech policy affects multiple ministries.

Government Policy on Biotechnology

The Chinese government has allocated significant resources to the research and development of biotechnology, particularly in the pharmaceutical and agricultural industries. Most if not all of this money is channeled through MOA. NDRC released *the 11th Five-Year-Plan on the Development of the Biotech Industry* in April 2007, which set the goals for the Chinese biotech industry by 2010, including: 1) the formation of a policy and regulatory framework that promotes technology innovation and technical standards that are favorable for biotech development; 2) the development of new IPR protected biotech products that would produce total annual sales of more than RMB 1 billion; 3) the formation of about 10 biotech enterprises each with annual sales of more than RMB 1 billion and 8 biotech industrial bases each with sales of more than RMB 50 billion; 4) the biotech industry would add approximately RMB 500 billion to China's GDP; and 5) significant increases of biotech exports. By 2020, the long term goal for the biotech industry is to develop IPR protected biotech products that would add an additional 2 trillion yuan or 4 percent to China's GDP.

In order to implement *the 11th Five-Year-Plan on the Development of the Biotech Industry*, the State Council issued *Policies to Promote Accelerated Development of the Biotech Industry* in June 2009. These policy guidelines required ministries and provincial governments to consolidate technical and financial resources to achieve the objectives outlined in the *11th Five-Year-Plan*. Highlights include transferring technology from publically funded institutions to leading biotech enterprises, providing financial support to establish biotech enterprises, and encouraging investment by overseas companies or individuals to establish research institutions and joint research projects. Local governments are required to increase financial and technical assistance to institutions to research and develop major transgenic crops. A government procurement system will be established to give priority to indigenously innovated biotech products. Governments at all levels should provide a 50 percent tax deduction for R&D expenses on new biotech products and a 15 percent corporate income tax deduction for biotech companies identified as high-tech enterprises. The document identifies five key areas for development: bio-pharmaceuticals, bio agriculture (ag-chemicals, feed, feed additives, fertilizer, and animal vaccines), bio-energy, and bio-environmental protection, and bio-service contracting.

Despite the State Council policy guidelines to increase investment, most of the 11th Five-Year-Plan biotech goals were not achieved by the 2010 deadline. China still has not fully commercialized any new major biotech products (other than cotton) for domestic production, does not export biotech crops, and no large private firms have become pillars for the biotech industry as most research and development still occurs at public research institutions. NDRC is finalizing the *12th Five-Year-*

Plan on the Development of Biotech Industry that stresses self-innovation capacity building in order to better develop the biotech industry. Among the five key areas of development, agricultural biotech plays an important role, with a focus on biotech seed breeding. In July 2011, The Ministry of Science and Technology (MOST) released The *12th Five-Year-Plan on the Development of Science and Technology*, which prioritizes the commercialization of new transgenic cotton and corn varieties.

Regulatory Framework

The biotechnology regulatory environment for agriculture is outlined in State Council regulations *"Food and Agricultural Import Regulations and Standard"* and *"Agricultural Genetically Modified Organisms Safety Administration Regulations 2001"* (See Gain Report CH1056) and implemented by MOA under Ministerial Decrees 8, 9 and 10. These decrees (*Measures on the Safety Evaluation Administration of Agricultural GMOs*, *Measures on the Safety Evaluation Administration of Agricultural GMO Imports*, and *Measures on Agricultural GMO Labeling Administration* (See Gain Report CH7053)) govern domestic approval, import approval, and labeling, respectively. SFA also released its *Review and Administration Measures on Conducting Activities Related to Genetically Engineered Forestry Wood Products* (Details can be downloaded at SFA website http://www.forestry.gov.cn/portal/main/s/26/content-204704.html)

The Chinese government is currently revising its biotech regulations. Details about the revision and timing of publication of the revised regulations are not publically available. The National Biosafety Committee has recently developed a guideline for biosafety assessment (environmental and food safety) to streamline the processes. The guideline can be downloaded at http://www.stee.agri.gov.cn/biosafety/zhbd/t20070913_782803.htm.

China and the Biosafety Protocol

The State Council ratified the Biosafety Protocol on April 27, 2005 and China participated in the discussion of MOP-3 (March 2006), MOP-4 (May 2008), and MOP-5 (October 2010) as a full member.

As the lead authority in implementing and developing Chinese regulations in compliance with the Biosafety Protocol, the Ministry of Environmental Protection (MEP) has not published any new or revised laws in accordance to the Protocol. MEP continues to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology. This exercise was not mandated by the State Council or any higher decision-making body, and was solely initiated by MEP.

Ministry of Agriculture: Labeling Policy

China's labeling regulations, governed by the Ministry of Agriculture Decree 10 (CH7053), require the labeling of approved agricultural biotech products and prohibits the importation and sale of any unlabeled or mislabeled products. The types of products subject to mandatory labeling include:

1. Soybean seed, soybeans, soybean powder, soybean oil, and soybean meal;
2. Corn seeds, corn, corn oil, and corn powder;
3. Rape seed for planting, rape seeds, rape oil, and rape meal;
4. Cotton seed;
5. Tomato seed, fresh tomato, and tomato paste.

Issues of Concern for MOA Biotech Regulations

Biotechnology Issues

- Asynchronous Approval - Current regulations require that biotech events be fully approved in the country of development before the Ministry of Agriculture (MOA) will accept an application for its registration to export the product to China. This requirement creates unnecessary delays in marketing and trading new biotech products already approved in exporting countries.

- Re-registration of Certificates- MOA biosafety certificates are valid for 5 and 3 years (non-food and food crops). Re-registration is cumbersome and contains certain unnecessary demands.

- Re-registration of Seed Samples – MOA requires seed samples for the renewal of biosafety certificates, even for varieties no longer marketed. This requirement is redundant and creates an unnecessary burden to maintain seed

stocks for products that are no longer commercially sold. If a few quantities of product are still in circulation after the certification expires, this may impede trade since China has a low level presence policy of 0 percent.

- Biosafety Certificates for Imported Products – Importers are required to obtain a MOA GMO biosafety certificate for all imports with biotech content, which adds an additional cost in shipping the product. The requirement does not provide any additional information to import quarantine officials beyond standard "may contain" shipping documentation. Importers of large-volume, bulk commodities routinely obtain certificates, but this practice varies among processed product importers.

- Low Level Presence (LLP) – Zero tolerance for unapproved varieties. The lack of an effective LLP policy constrains trade.

- Stacked Traits – China has no public policy outlining the approval process for stacked events, and all registrations are considered "case-by-case." The lack of a public policy creates concern over the long-term flexibility to deal with new generations of technology.

- Variety Based Registration – This current biotechnology registration system applies to both exports and domestically produced products. Variety based registration systems duplicate past safety evaluations and result in a less effective use of resources and a longer approval processes, especially as newer varieties incorporate previously approved technology. That being said, recently, China has started a new application process whereas an applicant can choose to register an event or a variety for domestic cultivation (not import). If a company registers a new event and it is approved through the regular process (3 production trials), a subsequent variety that uses the same event would only need to undergo 1 production trial in lieu of 3. Therefore, the deregulation time is shortened for the registration of a new variety that utilizes the previously registered event.

- Import Testing – AQSIQ randomly tests all products for GMO content. Importers have expressed concern with the testing effectiveness and consistency, as well as adherence to testing frequency guidelines.

- Proprietary Information in Biosafety Applications –
  During the biosafety application process, reportedly attempts have been made to require companies to provide sensitive, proprietary information. These inquiries appear to ask for more than what may be necessary to test the safety of new events.

Conventional Seed Issues

- Seed Registration – After MOA issues a biosafety certification for production, China requires either national or provincial variety registration before the planting seeds can be commercially sold or distributed nationally or within a specific province, which can take at least 2 to 3 years or longer. This process is duplicative and non-transparent.

- Plant Variety Protection – China has not acceded to UPOV91. (See GAIN Report CH11003).

Cross-Cutting Issues

- Investment Restrictions – China's State Council foreign investment catalogue stipulates that foreign investment in the conventional seed industry is a "restricted" activity (limiting foreign ownership of a joint venture to 49%) and foreign company development, production, or marketing of transgenic plants in China is a "prohibited" activity. (See GAIN Report CH7087)

- Intellectual Property Rights Protection - China's conventional seed and biotechnology regulatory and review mechanisms lack complete IPR protections and contain fundamental conflicts of interest that encourage weak IPR protection. For example, field trials for new products are conducted by Chinese research institutes that sometimes are also competing seed developers. Legal protections provided to applicants' genetic material appear insufficient to ensure complete confidentiality. Weak enforcement and low penalties for infringement weaken market protection for rights' holders.

Section IV. Plant Biotechnology Capacity Building and Outreach:

The U.S. and Chinese governments are working closely on several fronts to assist China in its capacity to effectively and fairly handle biotechnology. The U.S. - China High-Level Biotechnology Joint Working Group (BWG) was established in July 2002 as a way to address bilateral biotechnology issues of mutual interest. To supplement the policy discussions, a technical subgroup (TWG) was established in July 2003. The most recent BWG and TWG meetings were held in September 2011 in Beijing, China, with both sides committed to continued dialogue and collaboration on regulatory and technical exchanges on agricultural biotechnology.

Section V. Animal Biotechnology:

Research and Development of Genetically Engineered Animals in China

Public-funded research institutes or universities have developed or are researching transgenic animals, but none are approved for commercial production. The following are examples of ongoing research:

- The Heilongjiang Fishery Research Institute of Chinese Academy of Fishery Sciences has developed a transgenic carp utilizing a fish growth hormone gene which is under field trial and a mammal feeding study.
- The Institute of Hydrobiology of Chinese Academy of Sciences has also developed lines of transgenic triploid carp with genes of another fish that promote fast growth. This transgenic fish has been approved for field trial.
- Transgenic cows have been developed by China Agriculture University with either human lysozyme (hLY) gene/human fucosylated sugar transferase gene expression.
- Shanghai Genon Bio-engineering Co. Ltd has developed a transgenic goat that expresses either a human lactoferrin or lysozyme gene (both are single events). The first has been approved for an enlarged field trial and the latter is under restricted field trial.

Section VI. Plant Biotechnology Risk Communication Issues

Although some pre-2008 literature and surveys suggest that China's consumers were by and large open to and accepting of biotechnology products, the acceptance has been mixed in recent years due to lack of education and negative media reports, many of them by non-profit organizations. After China deregulated Bt rice and phytase corn in 2009, debate sparked over biotech food safety, risk communication, and the deregulation process.

One of the most recent surveys published in 2008 by the Asian Food Information Center (AFIC) stated that general Chinese consumer knowledge of biotech products was very low, and approximately only 45 percent of the population knew that GM products could be found in the grocery store. A lack of knowledge without factual support provides opportunity for propaganda to influence consumer beliefs. That being said, some Chinese government officials believe that because many Chinese consumers have little to no knowledge on biotechnology, and that the greater challenge is not alleviating consumer fears but finding more support within the Chinese scientific community since some researchers question the long term effects of the technology, such as on the environment. Regardless, greater efforts from the Chinese government to provide accessible and clear public information on the advantages and safety of biotechnology will be needed to gain support for GM foods. Otherwise, China may experience difficulty in fully realizing the benefits of biotechnology to help address its food security challenges.